REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed September 12, 2008 and entry of the present amendment is requested because Applicant respectfully submits that the Amendment places the application in condition for allowance or in better form for consideration on appeal.

Claims 1-15 and 23-34 remain pending with no claims currently amended. The listing of claims is provided merely for convenience.

In the Final Office Action, claims 1, 23, and 24 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. US 6,682,556 ("the Ischinger reference"). In addition, claims 1, 7-14, 23-31, and 33-34 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,749,890 ("the Shaknovich reference") in view of U.S. Patent No. 6,572,612 ("the Stewart et al. reference"), claim 15 was rejected under 35 U.S.C. § 103(a) as unpatentable over as unpatentable over the Shaknovich reference in view of the Stewart et al. reference, and further in view of U.S. Patent No. 6,766,186 ("the Hoyns et al. reference"), claim 32 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Shaknovich reference in view of the Stewart et al. reference in view of U.S. Patent No. 5,702,418 ("the Ravenscroft reference"), and claims 2-6 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Ischinger reference in view of U.S. Patent No. 6,589,214 ("the McGuckin et al. reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the § 102(b) rejections, as explained in Applicant's previous response, the Ischinger reference discloses a balloon catheter that includes a first guidewire channel 16 that

extends to the distal end 10 of the catheter beyond the balloon, and a second guidewire channel 14 with a distal exit 11 located adjacent the balloon. Col. 2, lines 56-63, col. 3, lines 10-13; FIGS. 1A, 2A. During use, a first guidewire 12 is placed in the target sidebranch artery and a second guidewire 15 is placed in the main artery. Col. 3, lines 59-63. The first guidewire 12 is threaded into the first channel 16, the second guidewire 15 is threaded into the second channel 14, and the catheter is advanced over the guidewires 12, 15 until the distal exit 11 of the second channel 14 reaches the bifurcation and prohibits further advancement. Col. 3, line 64 through col. 4, line 5. Alternatively, the second guidewire 14 may be preloaded in the second channel 14 and advanced through the distal end 11 once the catheter is inside the patient. Col. 4, lines 5-12. The feature 100 shown in FIGS. 2A, 4A, and 4B is merely described in the Ischinger reference as a pig-tail shape tip that optionally may be provided on the second guidewire 15. Col. 4, lines 29-34. The balloon catheter may be used to deliver a stent 40, 90 mounted on the balloon beyond the distal exit 11.

Turning to the present claims, claim 1 recites an apparatus for locating an interventional device relative to the ostium of a branch vessel that includes a sheath having proximal and distal ends, and a lumen extending therebetween, the sheath adapted to be affixed to an interventional device; and an ostial locator wire slidably disposed within the sheath, the ostial locator wire having a distal region initially provided in a retracted configuration within the lumen and that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region partially encircles and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen, the sheath being advanceable with the distal region in the expanded configuration to position the

interventional device relative to the ostium, the ostial locator wire and sheath being removable after positioning the interventional device.

The Ischinger reference does not disclose, teach, or suggest an ostial locator wire having a distal region initially provided in a retracted configuration within a lumen of a sheath and that assumes an expanded configuration when extended from the sheath such that the distal region ***partially encircles and is spaced apart from an interventional device*** when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen. The pig tail tip 100 of the guidewire 15 is ***structurally incapable of encircling*** anything. In particular, neither the guidewire 15 nor the pig tail tip 100 encircles the stent 40, 90 disclosed in the Ischinger reference. As clearly shown in FIG. 2A, at most, the guidewire 15 extends axially parallel to the stent 40, and the pig tail 100 extends away from the stent 40 and coils on itself. The coils of the pig tail 100 are clearly too small and incapable of partially encircling the stent 40, as can be seen in FIG. 2A. For these reason, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Ischinger reference.

For similar reasons, claim 23 is also neither anticipated by nor otherwise obvious over the Ischinger reference. Claim 23 also recites an ostial locator that assumes an expanded configuration when extended from the distal end of a sheath and ***partially encircles*** and is spaced apart from a stent. Such a locator is not taught or suggested by the Ischinger reference and the disclosed pig tail 100 is incapable of meeting the claimed structure, as explained above.

Turning to the rejections based on the combination of the Shaknovich and Stewart et al. references, the Shaknovich reference discloses an ostial stent delivery system or "shuttle" (1) that includes a catheter (4) having at its distal end a deployment segment (2) including a forward break

segment (3) and an expandable segment (5) on which a stent (6) is mounted. Col. 4, lines 50-56. The break segment (3) may be a balloon (3E, 3F), a Nitinol wire loop (7), or a pair of articulated wires (8) within a membrane. See FIGS. 3-5, col. 4, line 57 through col. 5, line 7.

During use, the shuttle (1) is advanced over a guidewire 14 through a guiding catheter 16 into a target artery (10) distal to an ostial lesion (9). Col. 5, lines 33-36; FIG. 9. The guiding catheter 16 and then the shuttle (1) are withdrawn from the target artery (10), and the break segment (3) is activated, i.e., expanded, as shown in FIGS. 10-12. Col. 5, lines 37-50. The deployment segment (2) is then advanced until the expanded break segment (3) comes to a stop against the wall of the parent vessel (15). Col. 5, lines 51-55; FIG. 13. The stent may then be expanded using an ancillary balloon catheter to expand the deployment segment or an expandable portion over which the stent is mounted is expanded to expand the stent in the target artery. Col. 8, lines 55-61, col. 10, lines 9-15.

With respect to claim 1, the Shaknovich reference fails to disclose, teach, or suggest an ostial locator wire, as is conceded on page 5 of the Office Action. More specifically, however, the Shaknovich reference does not teach or suggest a locator that is initially provided in a retracted configuration within a lumen of a sheath and that ***assumes an expanded configuration when extended*** from the sheath. Instead, the Shaknovich reference merely discloses a break segment that is activated to expand and collapse, e.g., by inflating a balloon or expanding wires within a membrane. Further, the Shaknovich break segment never ***partially encircles*** an interventional device affixed to the sheath. In contrast, the Shaknovich break segment is expanded adjacent, i.e., proximal, to a stent to help position the stent within the target artery. Thus, the Shaknovich reference is not deficient merely because it fails to disclose a wire.

The Stewart et al. reference fails to provide any additional teaching or suggestion that may be properly combined with the Shaknovich reference to render the present claims obvious. The Stewart et al. reference discloses a catheter assembly 190 for treatment of cardiac arrhythmia that includes a catheter body 192 that is ***deployable axially*** from a guide catheter or sheath 198. Col. 12, lines 32-37. The catheter body 192 includes a distal portion 202 carrying electrodes 194 for ablating tissue. Col. 12, lines 58-64. The catheter body 192 is virtually identical to catheter body 62, shown in FIG. 3A, which is intended to be disposed about a pulmonary vein ostium to ablate tissue surrounding the ostium. Col. 9, lines 11-30. col. 12, lines 42-48.

Thus, the Stewart et al. catheter assembly 190 has a structure, and not just an intended purpose, that is completely incompatible with the Shaknovich shuttle (1). The Stewart et al. reference discloses a catheter body 192 that is deployed axially from a sheath 198, whereupon a distal portion 202 of the catheter body 192 forms a coil 204. The Shaknovich reference does not disclose a lumen in the catheter (4) capable of receiving such a catheter body 192 that would allow the catheter body 192 to at least partially encircle the stent (6). Instead, the only lumen disclosed in the Shaknovich reference capable of receiving the Stewart et al. catheter body 192 would be the lumen that receives the guidewire (14) and balloon catheter (12), e.g., shown in FIGS. 10-12 of the Shaknovich reference. If, however, the Stewart et al. catheter body 192 were deployed from this lumen of the Shaknovich catheter (4), the coil 204 would extend distally beyond the entire apparatus and would not partially encircle the stent (6).

Further, neither of these references teaches or suggests how the catheter body 192 could be deployed at the location of the Shaknovich break segment (3) in order to allow the catheter body 192 to somehow be deployed to partially encircle the stent (6). The Shaknovich shuttle (1)

does not include a device lumen proximal to the stent (6), nor could a lumen be added to the Shaknovich shuttle (1) without substantially modifying the entire shuttle apparatus. Such an added lumen would need to be relatively large to accommodate the Stewart et al. catheter body 192 (which would necessarily have a relatively large diameter to carry the electrodes and related internal leads). A person of ordinary skill would realize that such a lumen could not be added to the Shaknovich catheter (4) given the already present guidewire lumen, which is necessary for delivering the catheter (4). Such a modification is not ordinary or predictable, but would be recognized by a person of ordinary skill as being a substantial and nonobvious change.

Further, if such a lumen were somehow added to the Shaknovich catheter (4) with a side opening proximal to the stent (6) and if the Stewart et al. catheter body 192 could somehow be deployed from this side opening (which is not taught in either of the Shaknovich or Stewart et al. references), the distal section 204 of the catheter body 192, when deployed, would extend axially sideways away from the Shaknovich shuttle (1) with the coils 204 disposed away from the shuttle (1). The Stewart et al. reference only discloses such axial deployment, and the structure of the catheter body 192 necessitates such axial deployment for the coils 204 of the catheter body 192 to be pressed against tissue surrounding a pulmonary vein ostium to ablate the tissue with the electrodes carried on the catheter body 192.

In order for the catheter body 192 to meet the claim language, the catheter body 192 would somehow need to completely change direction and bend upon being deployed from the Shaknovich catheter (4) and then somehow encircle the stent (6), which is not taught by the either reference. This is not a predictable result, but is in fact a substantial and nonobvious modification of the Shaknovich and Stewart et al. references. There is no apparent reason for making such a

modification other than the teachings of the present application, which constitutes improper hindsight. Therefore, even if the references could be properly combined (which Applicant disputes for the reasons given in the previous response filed on August 13, 2008), the resulting combination would not meet the structure recited in claim 1 without substantial further modification. Accordingly, for these reasons, claim 1 and its dependent claims are not obvious over the Shaknovich and Stewart et al. references.

For similar reasons, claims 23 and 29 are also not obvious over the Shaknovich and Stewart et al. references.

Finally, none of the Hoyns et al., Ravenscroft, or McGuckin references discloses, teaches, or suggests the features that are wholly absent from the Shaknovich and Stewart et al. references. Accordingly, the present claims are obvious even if these references could somehow be properly combined with the Shaknovich and Stewart et al. references (which Applicant does not concede).

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
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